REMARKS

In the Action, claims 1, 2, 4-7, 9-29, 31 and 41-43 are rejected. In response, claim 1 is amended to clarify that the polymerization initiator and polymerization activator are contained within the pores of the inorganic component and that the calcium phosphate has a specifically defined pore diameter, particle size and BET surface area.

In view of these amendments and the following comments, reconsideration and allowance are requested.

The Rejections

Claims 17 and 20 are rejected under 35 U.S.C. § 103(a) as being obvious over DE 199 39 403 to Schnabelrauch et al. The remaining pending claims are not listed in the rejection.

Applicants submit that independent claim 1 is not obvious over the art of record, and particularly DE '403. As noted in the Advisory Action, DE '403 does not disclose or suggest a porous bioabsorbable inorganic filler or a porous calcium phosphate having pore diameters, particles sizes and BET surface area as recited in claim 1. DE '403 teaches that the pores develop in the polymeric matrix after reabsorption of the inorganic filler under *in vivo* conditions.

DE '403 provides no suggestion to one skilled in the art that the materials are porous. DE '403 specifically discloses the bioabsorbable materials identified as components B and C are selected from calcium carbonate, magnesium carbonate, calcium phosphate, hydroxyapatite and mixtures thereof, with calcium carbonate being preferred.

Nothing in DE '403 suggests to one skilled in the art that the inorganic fillers are porous. Applicants respectfully submit that the Action does not present any evidence to support the

assertion that the fillers of DE '403 are porous. The disclosure of various fillers such as the preferred calcium carbonate does not suggest porous fillers.

Moreover, DE '403 expressly discloses that the monomer-containing reaction mixture is coated onto the surface of the particles. DE '403 does not disclose the reaction mixture being contained within pores of the particles. DE '403 consistently refers to the fillers as solids to produce a solid material that can be processed by conventional machining processes, such as drilling, milling, turning or sawing.

DE '403 clearly fails to disclose a porous implant material that is porous at the time of implantation. The implant of DE '403 is a solid material defined by the inorganic filler and the polymer component. The implant of DE '403 is initially a solid matrix where the pore system in the composite material is created *in vivo* by resorption of the inorganic filler, thereby leaving the crosslinked polymer matrix with the pores formed therein. Thus, the pores of the material of DE '403 are formed in the polymer matrix and not in the inorganic filler. The inorganic filler of DE '403 has a rate of resorption that is faster than the rate of resorption of the polymer matrix so that the pores form in the polymer matrix. Thus, the pores in the implant material are formed after several months in the slower resorbable crosslinked polymer matrix.

DE '403 further fails to disclose or suggest a water-soluble pore-forming substance as recited in claim 1. DE '403 is silent with respect to pore forming materials.

The Action refers to sodium bicarbonate of Example 1 of DE '403 as allegedly disclosing a pore-forming material. The passage referred to in Example 1 discloses extracting the reaction mixture twice with 50 ml of 1 N-hydrochloric acid, twice with 100 ml saturated sodium bicarbonate solution and three times with 100 ml of water. Nothing in Example 1 suggests a pore-forming material. The extraction of the reaction product with a saturated solution of sedum

bicarbonate does not form pores and the saturated extraction liquid does not function as a pore-forming material. Moreover, the saturated solution is not part of the self-hardening bioabsorbable composite material.

Examples 4 to 6 of DE '403 disclose the preparation of the composite materials. There is no disclosure of a pore-forming substance. Instead, DE '403 only discloses non-water soluble thickeners such oligo-L-lactide and resorbable non-water-soluble fillers.

Claim 1 specifically recites a calcium phosphate having a pore volume accessible to the polymerization initiator of 0.4 cm^3/g or more and having a specifically defined pore diameter, particle size and BET surface area. DE '403 does not disclose or suggest the combination of these features. DE '403 does not disclose a polymerization initiator and/or polymerization activator being drawn into the pore system as disclosed on page 17 of the present specification.

DE '403 only discloses "coating" the inorganic filler but does not disclose or suggest the claimed method of producing a self-hardening bioabsorbable composite material by introducing a polymerization initiator and polymerization activator into the pores. DE '403 does not disclose the specific calcium phosphate as claimed. DE '403 is silent regarding the properties or characteristics of the calcium phosphate and other inorganic materials and clearly fails to disclose a porous calcium phosphate as in the claimed invention. The behavior of the resulting cement is strongly dependent on the filler. One skilled in the art would have no reasonable expectation that a porous material would be effective, particularly in view of the known and widely recognized disadvantages of porous filters.

DE '403 refers only to bioabsorbable inorganic fillers with calcium carbonate being preferred and does not suggest a porous calcium phosphate having a pore diameter, particle size or surface area as claimed.

The Action does not provide an adequate factual basis or reasonable rationale to support the assertion that the claimed calcium phosphate would have been obvious to one of ordinary skill in the art based on the disclosure of DE '403. DE '403 does not disclose calcium phosphate having a pore volume or pore diameter that is able to receive a polymerization initiator and/or polymerization activator. DE '403 refers only to coating the particles. One skilled in the art would not reasonably interpret the "inorganic fillers" as satisfying the claimed requirements of the calcium phosphate having a pore volume of 0.4 cm^3/g or more, pore diameters of diameters of 0.1 to 500 μm, particles of 1 to 500 μm, and a BET surface area of at least 0.1 m^2/g as recited in claim 1. The Action does not address these aspects of claim 1 and fails to provide an adequate basis to support the conclusion that these features would have been obvious to one skilled in the art. Accordingly, Applicants respectfully submit that the Action has not established prima facie obviousness of independent claim 1.

The porous materials in a fully bioabsorbable composition of the invention have advantages over the non-porous materials such as those conventionally used in DE '403. The porous calcium phosphate of the present invention enables the growth of cells in the pores which result in better adhesion and anchoring of bone cells and provide a direct bonding between the bone tissue and the bioabsorbable composite material at the interface without the formation of an interlayer of connective tissue. The porous materials of the present invention exhibit a faster integration into the bone tissue.

The porous biodegradable materials of the claimed invention contain an *in situ* hardening polymer and a resorbable bioinorganic filler that has a faster rate of biodegradation due to the large surface area of the materials. The pores of the resorbable bioinorganic filler are accessible to degrading media such as water, dissolved salts and enzymes, thus enabling the bone

regeneration material to be resorbed faster. The porosity of the claimed filler material is an important aspect of the invention to improve and accelerate the biodegradation of the bioabsorbable composite material as a result of the polymers generated by the *in situ* hardening of the polymerizable monomers.

The dependent claims are also not obvious for reciting additional features of the invention that are not disclosed or suggested in combination with DE '403. For example, DE '403 does not disclose the modifying constituents of claim 2, the viscosity adjusting component of claims 4-6, one of the components reacting in water to form a water-soluble product as in claim 7, the use of sodium hydrogen carbonate as a pH modifying agent and pore-forming substance as in claim 9, one of the constituents acting as an adhesion-imparting agent of claim 10, the polymerization initiator mixed with the bone regeneration material in an amount of 0.1 to 20% by weight as in claim 18, the polymerization initiator being an organic peroxide as in claim 19, the amount of the polymerization initiator of claim 21, the specific polymerization activators of claim 22, or drawing the polymerization activator into the bone regeneration material as in claim 23, in combination with the features of claim 1. As noted above, DE '403 discloses coating the particles and does not disclose or suggest the polymerization activator being absorbed into a porous particle. DE '403 specifically discloses a coated particle, and thus, does not disclose removing the excess amount of the polymerization activator as specifically recited in claim 23.

DE '403 also does not disclose the inorganic bone regeneration materials of claim 24, immobilizing the polymerization initiator in the bone regeneration material as in claims 25 and 26, the pore volume of the calcium phosphate of claim 28, the specifically defined calcium

phosphate of claim 29, or the monomers of claim 31, either alone or in combination with the features of claim 1.

Claims 17 and 20 are also not obvious over DE '403. DE '403 does not disclose a solution of the polymerization initiator where the solution is allowed to infiltrate the bone regeneration material and drying the bone regeneration material as in claim 17, or forming a melt or solution of the polymerization activator added to the regeneration material to infiltrate the bone regeneration material, and drying the bone regeneration material as in claim 20, in combination with the features of claim 1.

On page 12 of the Action, claims 12-14, 16, 24, 27 and 28 are rejected under 35 U.S.C. § 103(a) as being obvious over DE '403, and further in view of U.S. Patent No. 4,373,217 to Draenert. Draenert does not specifically disclose a colorant or contrasting agent as in claim 12, a pharmaceutically active ingredient as in claim 13, the active ingredient being antibiotics, anti-inflammatories, growth factors and/or cancerostatics as in claim 14, in combination with the method steps of claim 1.

Draenert also does not disclose the bone regeneration material in the form of powder or granules as in claim 16, the inorganic materials of claim 24, the properties of the calcium phosphate of claim 27, or the properties of the calcium phosphate of claim 28, in combination with the method steps of claim 1.

Draenert is cited for disclosing calcium phosphate as a filler material. Draenert discloses the calcium phosphate having a large pore volume in the order of 0.3 to 0.5 ml/g that is outside the claimed range. These calcium phosphates are normally relatively soft as disclosed in column 3, lines 50-52, and exhibit numerous disadvantages as disclosed in column 3, line 58, to column 4, line 12. Polymerization of the acrylate or methacrylate monomers in such particles is often

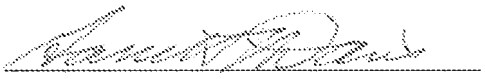
incomplete so that there is a risk that the relatively large proportion of residual acrylate and methacrylate monomer will remain uncured. DE '403 and Draenert both use a non-porous bioabsorbable filler to avoid these problems.

Draenert does not disclose the claimed porous calcium phosphate as suggested in the Action. Draenert specifically uses a calcium phosphate having a pore volume below 0.1 ml/g, and preferably below 0.05 ml/g, and thus, avoids the use of the porous calcium phosphate. The pore volume of Draenert is obtained by precipitating tricalcium phosphate as a starting material having a pore volume of 0.35 ml/g and 0.4 ml/g. See, for example, Example 3A in column 4, lines 44-60. The tricalcium phosphate starting materials are annealed at elevated temperatures. Draenert discloses mixing the annealed starting materials having a pore volume below 0.1 ml/g with the polymerizable monomers. In Example 1, Draenert discloses filling the pores of the porous calcium phosphate with glycerin, thereby reducing the pore volume to less than 0.1 ml/g.

Draenert further relates to a bone cement that is not resorbed by the body. One skilled in the art would recognize that the Draenert product does not suggest the claimed bioabsorbable composite material. Draenert is directed to an implantation material that has an opposite mode of action to that of the claimed invention. Thus, Draenert is unrelated to DE '403 and is unrelated to the claimed invention. Accordingly, the claims are not obvious to one skilled in the art either standing alone or in combination with DE '403.

In view of the above comments, the claims are submitted as being allowable over the art of record. Accordingly, reconsideration and allowance are requested.

Respectfully submitted,



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